

METHOD AND DEVICE FOR TREATING MICROSCOPIC RESIDUAL TUMORS REMAINING IN TISSUES FOLLOWING SURGICAL RESECTION

RELATED APPLICATIONS

[0001] This application claims the benefit, under 35 U.S.C. § 119(e), of: U.S. Provisional Patent Application No. 60/778,740, which was filed on Mar. 3, 2006, was of same title and named Paul Goldfarb and Dietmar Rabussay, as inventors. The entirety of this application and document is incorporated by reference.

FIELD OF THE INVENTION

[0002] This invention relates to electroporation systems, devices and methods of using such devices for treating tissues surrounding sites of tumors. More specifically, this invention relates to the debulking of tumor masses, sparing of tissue surrounding tumors and reducing tumor mass size and recurrence rates by treating apparently non-cancerous tissues with electroporative pulses and anticancer agents.

BACKGROUND OF THE INVENTION

[0003] The following description includes information that may be useful in understanding the present invention. It is not an admission that any such information is prior art, or relevant, to the presently claimed inventions, or that any publication specifically or implicitly referenced is prior art.

[0004] Except for vascular disease, cancer is the most frequent cause of death in industrialized countries. The traditionally accepted paradigm for treating cancers and tumors that comprise a single relatively well defined tissue mass has included the use of radiation and chemotherapy typically in association with surgical removal. In cases where surgical resection is an option, surgery is usually the most effective form of treatment. However, the effectiveness of surgical treatment depends on the complete removal of malignant tissue, encompassing the main tumor mass as well as branches and micrometastases which are frequently present in the vicinity of the main tumor.

[0005] When removing the main tumor, the surgeon also attempts to eliminate such local or regional micrometastases by resecting apparently normal tissue surroundings the tumor. That tissue is referred to as “margin tissue” or simply as “margin.” To what extent margin tissue is removed is subject to the surgeon’s judgment. Typically, a margin of 0.5-2 cm around the entire tumor is acceptable. However, more extensive resections are not uncommon for invasive tumors. Even after careful resection of the tumor and margin, most types of tumors recur with a frequency of 10-40%. The recurrence rate depends on multiple factors including tumor size, type and location of the tumor, condition of the patient, etc. In order to reduce the rate of recurrence, surgery is usually followed by radiation and/or chemotherapy. Despite such secondary treatments recurrence rates are still uncomfortably high.

[0006] In addition to surgery and radiation, other methods of local tumor control are in use. These include Radiofrequency (RF) Ablation, Photodynamic Therapy (PDT), Cryotherapy (CRYO), Chemo-Radiation (CR), Brachytherapy (BT), Galvanotherapy (GT), and others. Surgery, RF, PDT, CRYO and CR rely on the complete removal or destruction of the tumor and margin tissues, whereas radiation, BT, and

GT leave treated normal tissue more or less intact, although radiation and BT may cause severe scarring, fibrosis and vascular and neural damage. In any event, removal, scarring, and physical damage of healthy tissue can result in substantial disfigurement and substantial loss of physical use of body parts and/or functionality thereof. For example, most of the above listed current adjuvants to surgery for destroying or removing tumor masses cause nonspecific damage to normal tissues surrounding the tumor. Excision of a tumor mass can be completely debilitating to function where tumors must be removed from organs including the tongue, vocal chords, rectum, labia, penis, or to fine muscle and visual structures of the face tissue.

[0007] To avoid such disfigurement and preservation of function and to ensure that tissues surrounding the tumor are cleared of such cancerous cells, the present invention is provided as an adjuvant or neo-adjuvant to surgery as there is still a need in the oncology arts for a device and method of sparing apparently healthy tissues that lie adjacent to tumors and to reduce tumor mass, growth of the tumor, and recurrence rates.

SUMMARY OF THE INVENTION

[0008] In a first embodiment, the invention comprises a method of reducing the probability of recurrence of cancer cell growth in a tissue. In a preferred embodiment, the method includes providing to the cells of said tissue both an electroporating pulse of electric energy and a medicament. In a related embodiment the medicament is preferably provided to the tissue immediately prior to or simultaneously with the electroporating pulse.

[0009] In a second embodiment, the invention comprises a method of treating residual cancerous cells remaining in tissues following surgical resection. Preferably, the invention provides for controlling further spreading of cancer by subjecting microscopic nodules or other forms of cancerous tissue to the medicament in an electroporating electric field. In a related embodiment, such treatment can be an adjuvant to surgery in that it can be applied either prior to or after tumor removal. In some circumstances, especially where the cancerous cells have not yet formed into a fibrous mass, no surgical procedure may be employed. In such case, the EP treatment provides a method to reduce tumor mass and terminate or delay further growth of cancerous cells in the tissue. In still a further related embodiment, the invention methods provide for debulking of larger tumor masses by causing through the effect of an anticancer agent, such as Bleomycin, a ‘softening’ of the tumor tissue such that the tumor mass will be easier to remove from surrounding healthy or normal tissue.

[0010] In a third embodiment, the invention method provides for decreasing the amount of normal tissue surrounding a tumor site, i.e. the “margin” tissue, that must be removed at the time of tumor excision and thereby spare normal tissue and consequently provide for greater retention of tissue function, and appearance.

[0011] In still other embodiments, the invention provides an instrument that is capable of providing said electroporating energy pulses to the tissue surrounding an excised tumor on demand and in an easily operable manner. In related embodiments, the invention device provides for both administration of an anti-cancer agent and administration of electric fields sufficient to cause electroporation of the